

MATUTECH, INC.

PO Box 310069
New Braunfels, TX 78131
Phone: 800-929-9078
Fax: 800-570-9544

Notice of Independent Review Decision

DATE OF REVIEW: FEBRUARY 5, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Intrathecal pump to be filled with Prialt (ziconotide) on a three-month trial.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

The physician providing this review is a Doctor of Medicine (M.D.). The reviewer is national board certified in Physical Medicine and Rehabilitation as well as Pain Medicine. The reviewer is a member of International Spinal Intervention Society and American Medical Association. The reviewer has been in active practice for ten years.

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

Overturned (Disagree)

Medical documentation supports the medical necessity of Intrathecal pump to be filled with Prialt (ziconotide) on a three-month trial

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Texas Department of Insurance

- Utilization reviews (12/19/07 – 12/31/07)

Services, Inc.

- Office notes (01/29/07 - 01/03/08)
- Diagnostic (01/29/07)
- Utilization reviews (12/19/07 – 12/31/07)

No reference to Prialt in ODG or ACOEM, hence not utilized.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who was injured. She reported that an obese person fell backwards from a standing position on her. With this impact, she fell against a wall and then slumped to the floor with the person lying on her right shoulder and arm. Paramedics asked her not to move while she was being rescued.

No records from 2003 through 2006.

In January 2007, M.D., a neurologist, evaluated the patient for neck pain and difficulties with her extremities due to diabetes and reflex sympathetic dystrophy (RSD). She was on a Dilaudid pump, Topamax, Lexapro, Klonopin, and insulin. Dr. performed an electromyography (EMG) that revealed evidence of bilateral radial nerve injury.

D.O., a pain specialist, noted swelling and pseudomotor or vasomotor changes in the extremities. He refilled the pump with Dilaudid and adjusted it at a dose of 4.6 mg/day. In March, he replaced the pump as it had become less effective. He adjusted the dose of Dilaudid to 1.9 mg/day. He suggested possible treatment with intrathecal Prialt (ziconotide) or SNX-111. The patient had continued swelling, hyperesthesia, and allodynia throughout the lower extremities with obvious color changes and edema. Her medications included antidepressant and neuropathic pain medications. Dr. felt these changes were consistent with stage 2 complex regional pain syndrome (CRPS). The patient also developed headaches as well as allodynia and contact skin lesions. Dr. gradually increased the Dilaudid dose to 2.5 mg/day. However, the patient had symptoms of mental fatigue, insomnia, visual disturbances, and gastrointestinal (GI) disturbances. He believed these were consistent with centrally-spread CRPS and gradually decreased the dose of Dilaudid to 0.8 mg/day in anticipation of the Prialt therapy. The patient was maintained on Lyrica, Klonopin, Paxil, and MS Contin. Dr. suggested proceeding with the Prialt therapy as the patient was getting only 40-50% relief with Dilaudid.

On December 19, 2007, the request for three-month trial of Prialt therapy was denied with the following rationale: *Prialt is indicated for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatment such as systemic analgesics, adjunctive therapies, or intrathecal morphine. Records do not reflect enough information to support an indication for this new treatment.*

On December 31, 2007, the request for reconsideration of Prialt therapy was denied with the following rationale: *Documentation does not support failed trial of morphine or hydromorphone. Documentation does not support that claimant is having side effects or no effectiveness from morphine or hydromorphone to support a trial of Prialt.*

On January 3, 2008, Dr. evaluated her for complaints of generalized edema in the upper and lower extremities, insomnia, global hyperesthesia, allodynia, GI disturbances, and effects consistent with disseminated CRPS. He stated the patient had recently been admitted to a hospital and was evaluated for four days and no anatomic lesion was determined. The patient was barely able to perform

her daily activities. Dr. stated that she had failed intrathecal narcotic therapy and neuropathic and centrally-acting alpha-adrenergic agents to the point where Prialt therapy was indicated.

On January 21, 2008, Dr. noted edematous legs, dermatological changes, and emotional changes. He recommended bilateral lumbar sympathetic blockade for treating fluid retention (patient's cardiologist had a hard time treating her fluid retention) and stated that until the sympathetics were treated, the swelling would persist. He stated he had weaned her off the narcotic analgesics because of unpleasant side effects such as edema and poor analgesia. Treatment with Prialt therapy was again stressed. The patient was on MS Contin, Topamax, and Paxil. He increased the dose of MS Contin to 60 mg b.i.d. The patient was going to follow-up with other doctors for generalized edema, skin breakdown, and possible cellulitis of the lower extremities.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

Tertiary treatment with Prialt appears to be indicated based on a careful review of documentation. The patient had primary and secondary treatments including Morphine and Dilaudid. The patient should be made fully aware of the risks and benefits of treatment including the black box warning, and this should appear on the consent form. The treatment is supported fully by literature, by consensus, and by ODG when given in the correct context of risk vs benefit.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**